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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,211	03/17/2006	Kiyoshi Matsumoto	740165-390	3936

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Intellectual Property Department

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EXAMINER

WOOD, ELLEN S

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

09/22/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/525,211

Applicant(s)

MATSUMOTO ET AL.

Examiner

ELLEN S. WOOD

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiess et al. (US 6,251,489, hereinafter "Wiess").

In regards to claim 1, Wiess discloses a sterilizable flexible pouch package that houses medical devices or instruments (col. 1 lines 10-19). There is a lower web 11 that is adhered to intermediate web 12 that will support the weight of an object in the pouch (col. 6 lines 54-56 and figs. 8-9). The intermediate web 12 is considered the protective component that is disposed in the inner surface. The bag has lower and side edges that are formed from gas-permeable material and a synthetic resin film with an opening in the upper end (col. 4 lines 24-67). The lower web 11 is formed from a flexible steam-permeable barrier web which provides an effective barrier against the migration of micro-organisms (col. 6 lines 27-30). Web 12 which is bonded to the inner surface of web 11 will support the weight of an object in the pouch (col. 6 lines 52-56). The layering system can be seen in figures 2-4, and it can be seen that the web 12 is bonded to the gas permeable material and will catch the contents of the bag (figs. 2-4).

In regards to claim 8, Wiess discloses that the protective component is a multilayer film (col. 4 lines 31-61).

In regards to claim 11, Wiess discloses that the protective component is made to be pervious to permit the sterilizing fluid to pass through the web (col. 9 lines 18-21).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiess et al. (US 6,251,489, hereinafter "Wiess").

In regards to claim 12, Wiess discloses the bag as previously presented but is silent with regards to the type of medical instruments contained within the bag. Wiess discloses that the invention relates to packages that permit sterilization of heavy objects (col. 1 lines 16-19). The packages are designed to with stand large weights and oddly shaped instruments, thus it would be obvious to one of ordinary skill in the art that the

packages of Wiess could withstand a the force of smaller weight objects such as scalpels, tweezers, forceps and scissors.

6. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiess et al. (US 6,251,489, hereinafter "Wiess") in view of Ota (JP 08-168518).

Wiess discloses the bag as previously present but is silent with regards to the folding of the protective component.

Ota discloses a bag for sterilization for forceps, tweezers, scissors, etc. [0001]. The bag is comprised of a natural synthetic resin film [0014] adhered to a back side sheet of material that is gas-permeable [0023 and 0026]. The bag has an opening at the top (drawing 4). The bag has damage prevention means by having a basilaris ossis occipitalis (boat bottom) formed at the bottom of the bag [0016]. This provides for standing of the bag and the contents of the bag will hit the lower part of the bag, which receives the weight [0036]. Since, the bag is formed from natural synthetic film the bag will not separate, thus preventing the contents of the bag from puncturing the bottom of the bag [0036]. The bottom of the bag is formed from folding a third piece of rectangle natural resin [0013]. The piece is folded in half so that it may become symmetrical by a line parallel to said two sides of opposite and that it can be positioned so that it may be put between pieces of a rectangle of two, and a field which sandwiches said inward line for this 3rd piece of rectangle to form the boat bottom[0011]. The examiner would also like to draw the attention to drawing 7 and the lines that are present for the folding explained previously. The examiner considers this mountain and valley folding based on

the definition that mountain folding is folding away from the outer layer and valley folding is folding towards the outer layer.

Ota discloses that pouch package can be square, oval, round, and of virtually any desired shape (col. 12 lines 15-18). It would be obvious to one of ordinary skill in the art to use the folding techniques of Ota with the packaging system of Wiess to form a package that has enhanced strength and permeability that can be used for the sterilization of medical instruments such as scalpels, tweezers, forceps and scissors.

Response to Arguments

7. Applicant's arguments with respect to claims 1 and 8-12 have been considered but are moot in view of the new ground(s) of rejection.
8. Claims 2-7 have been cancelled.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLEN S. WOOD whose telephone number is (571)270-3450. The examiner can normally be reached on Monday-Friday 7-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ellen S Wood
Examiner
Art Unit 1794

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/Carol Chaney/
Supervisory Patent Examiner, Art Unit 1794